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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,613	02/28/2006	Andrew John Eatherton	P33118USW	4037

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EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/528,613	EATHERTON ET AL.	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Most notably, Applicants, in claims 1 and 2, use the phraseology "... or a pharmaceutically acceptable derivative thereof" and this language extends to remaining claims 3-17. However, the Applicants' specification merely defines a pharmaceutically acceptable derivative to mean "any pharmaceutically acceptable salt, ester, salt of such ester or solvate of the compounds of formula (I) or any other compound which upon administration to the recipient is capable of providing (directly or indirectly) a compound of formula (I) or an active metabolite or residue thereof" (Applicants' Specification at Page 8, lines 8-15).

This language does not permit those of skill in the art to ascertain the metes and bounds of the Applicants' invention, as the disclosure is written in such a way that any compound, even if capable *indirectly* of providing a compound of the formula (I) or an active metabolite or *residue* was contemplated at the time of the invention. The same is not supported and therefore, the claims are rejected for failure to meet the written description requirement.

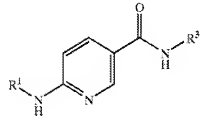
Claim Rejections – 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6, 7, 8, 9, 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated U.S. Patent No. 6,184,237 [hereinafter referred to as "Mantlo et al"].

Mantlo et al disclose the following compound

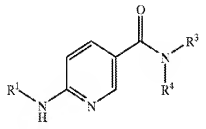


where R^1 may be phenyl and R^3 may be o-tolyl (Col. 86, Table 8, lines 1-14). With these substituents, claims 1, 3 and 4 of the instant invention are clearly anticipated where R^1 and R^2 together with N to which they are attached form a 4- to 8- membered non-aromatic heterocyclyl ring. Mantlo et al also teach that the compounds of its invention or pharmaceutical compositions thereof are useful in the treatment of rheumatoid arthritis, osteophorosis, multiple myeloma, acute and chronic myelogenous leukemia, osteoarthritis, inflammatory bowel disease, bone resorption diseases, atherosclerosis, multiple sclerosis, myalgias due to infection, cancer, and pain disorders (Col. 98, lines 7-37). The treatment methodology comprises the administration of an effective dose of the compound a pharmaceutical salt thereof or a pharmaceutical composition thereof to a human subject (Col. 98, lines 47-52). That there is the same anticipated patient population being administered the same compounds and compositions as taught by the instant invention's claim 1, it logically flows that the conditions are mediated by the activity of cannabinoid 2 receptors, which collectively with all of the other foresaid disclosures, too brings claims 6-11 within the purview of Mantlo.

In view of the foregoing, claims 1, 4, and 6-11 are clearly anticipated.

Claims 2 is rejected under 35 U.S.C. 102(b) as being anticipated Mantlo et al.

Mantlo et al. teach the following compound and the compound as the active ingredient in a composition



(Col. 84, Example 19), where R^1 can be 4-chloro-2-methylphenyl and R^3 can be o-tolyl (Col. 86, Table 8, line 15), which brings the instant invention within the purview of Mantlo et al, most especially when R^1R^2N is a non-aromatic heterocyclyl and nitrogen attaches to a halo-substituted phenyl ring and R^4 and R^6 are hydrogen.

In view of the foregoing, claim 2 is clearly anticipated.

Claim Rejections – 35 U.S.C. §103(a)

The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this Office Action:

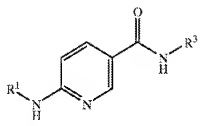
> (a) A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

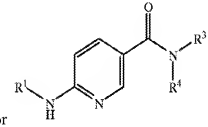
claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 and 12-17 are rejected under 35 U.S.C. §103(a) as being obvious over Mantlo et al.

Mantlo et al disclose that the compounds of its invention, encompassing the following core structures



or



or pharmaceutical compositions inclusive thereof are useful in the treatment of rheumatoid arthritis, osteophorosis, multiple myeloma, acute and chronic myelogenous leukemia, osteoarthritis, inflammatory bowel disease, bone resorption diseases, atherosclerosis, multiple sclerosis, myalgias due to infection, cancer, and pain disorders (Col. 98, lines 7-37). The treatment methodology comprises the administration of an effective dose of the compound a pharmaceutical salt thereof or a pharmaceutical composition thereof to a human subject (Col. 98, lines 47-52).

While the compounds of instant claim 12 are cot taught explicitly, their core structure, and synthesis of 6-(substituted-amino)-N-substituted nicotinamides are taught therein, along with numerous modifications that invariably lead on of ordinary skill in the art to make modifications that will not diminish the effectiveness of compounds in their function. For example, there are more than 100 compounds with the same core structure, but varying substituents, but they all treat the same diseases and disorders.

In light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that administering effective amounts of the compounds and compositions of the instant invention, rheumatoid arthritis, osteophorosis, multiple myeloma, acute and chronic myelogenous leukemia, osteoarthritis, inflammatory bowel disease, bone resorption diseases, atherosclerosis, multiple sclerosis, myalgias due to infection, cancer, and pain disorders would be successfully treated.

Conclusion

None of the pending claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Raymond J Henley III/
Primary Examiner, Art Unit 1614